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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ernest A. Voisin

Serial No. 09/121,725

Group Art Unit: 1761

Filed: July 24, 1999

Examiner: Drew Becker

For: "A Process of Elimination of Bacteria in Shellfish..."

Date: September 19, 2000

To the Honorable Commissioner
Of Patents and Trademarks
Washington, D.C. 20231

Box: Fee (Patents)

RESPONSE

Sir:

This is a response to the Office Action of May 19, 2000. A shortened statutory period for response to the Office Action was set to expire three months from the date of the letter, making a response due on or before August 19, 2000. A one-month request for extension of time along with an appropriate fee of $55.00 is enclosed herewith, making a due date for response September 19, 2000.

Claims 3, 4, 6 and 7 are pending in the application. Allowability of these claims was withdrawn following applicant's submission of the Information Disclosure Statement on January 10, 2000.

Claims 6 and 7 were rejected under 35 USC 102(b) as being anticipated by JP 4356156A. Examiner admitted that the cited reference does not teach elimination of pathogenic *Vibriones*. However, Examiner reached a conclusion that "the claimed characteristic of eliminating pathogenic *Vibriones* bacteria is considered an inherent

property and result of the referenced method, and not unique to the instant invention, absent any clear and convincing evidence or arguments to the contrary. "

The applicant respectfully traverses this rejection and submits that JP 4356156A does not anticipate claims 6 and 7. To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. See, *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047, 34 USPQ2d 1565, 1567 (Fed. Cir. 1995). Anticipation is an issue of fact, see *In re Graves*, 69 F.3d 1147, 1141, 36 USPQ2d 1697, 1700 (Fed. Cir. 1995); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988), and the question whether a claim limitation is inherent in a prior art reference is a factual issue on which evidence may be introduced, see *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

To serve as anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. However, such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. *In re Oerlich*, 666 F.2d 578, 581, 212 USPQ 323,326 (CCPA 1981); *Hansgirg v. Kemmer*, 102 F.2d 212, 213, 40 USPQ 665, 667 (CCPA 1939). An inherent disclosure, to be invalidating as an "anticipation," is a disclosure that is necessarily contained in the prior art, and would be so recognized by a person of ordinary skill in that art. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 USPQ2d 1746, 1749-50 (Fed. Cir. 1991).

Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *Hansgirg v. Kemmer*, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939); *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 51 USPQ2d 1001 (Fed. Cir. 1999). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1656, 1571, 230 USPQ 81, 84 (Fed. Cir. 1986).

Rejections under 35 USC 102 are proper only when claimed subject matter is identically disclosed or described in prior art, in other words, all material elements recited in the claim must be found in one unit of prior art to constitute anticipation. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978). An accidental or unwilling duplication of an invention cannot constitute anticipation. *Id.* The law of anticipation requires that the same invention, with all the limitations of the claims, existed in the prior art. See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920-21 (Fed. Cir. 1989) ("anticipation" requires that the identical invention is described in a single prior art reference).

"Inherency" charges the inventor with knowledge that would be known to the art, although not described. Inherency is not a matter of hindsight based on the applicant's disclosure: the missing claim elements must necessarily be present in the prior art. *In re Zurko*, 111 F.3d 887, 42 USPQ2d 1476 (Fed. Cir. 1997).

JP 4356156A discloses a process of opening a shell of raw unshucked shellfish, for example an oyster using high-pressure processing. Claims of the instant application recite a method of eliminating pathogenic organisms in raw molluscan shellfish. JP

4356156A was initially cited in the International Search Report conducted by the European Patent Office in the corresponding PCT application of this applicant.

The authorized officer of the European Patent Office, the designated International Searching Authority, classified JP 4356156A as a reference defining the general state of the art which was not considered to be of particular relevance (category "A"). This is strong evidence that at least one person "of ordinary skill in the art" recognized the cited reference as not defeating novelty of the present invention.

The applicant submits additional evidence, testimony of people having "more than average" skill in the relevant art. The first evidentiary material is a copy of a letter from Robert L. Collette, Vice-President of Science and Technology of the National Fisheries Institute (Exhibit A). In the letter, Mr. Collette characterizes Mr. Voisin's invention as a "breakthrough needed to correct the problem" [of reduction of *Vibrio Vulnificus* bacteria]. According to Mr. Collette, the new process "is truly impressive when considering the amount of time and money spent by universities and scientists worldwide to solve this concern."

The second evidentiary material is a copy of a letter from Michael W. Moody, Ph. D., Seafood Technologist of the Louisiana State University Agricultural Center (Exhibit B). After introducing his impressive credentials, Dr. Moody describes the problem of raw molluscan shellfish contamination by *Vibrio Vulnificus*. Dr. Moody stated that "prior to Mr. Ernest Voisin contacting him about the possibility of using high pressure treatment for the elimination of *Vibrio Vulnificus* in raw molluscan shellfish, [he] was not aware of the process being used anywhere or by anyone for that purpose." Dr. Moody continues to state that he "was not aware of anyone suggesting that the process be used for that

purpose." This is additional evidence that a "person of ordinary skill in the art" considers the instant invention novel and nonobvious.

In an effort to properly evaluate the teachings of the cited reference, the applicant secured a copy of the prosecution file history of JP 4356156A from the Japanese Patent Office and had it translated. A copy of the file history and the translation is attached as Exhibit C to this Response.

As is clearly demonstrated by the file history, the cited reference does not address the problem of shellfish contamination by *Vibriones*. The cited reference does not disclose a step of "eliminating pathogenic *Vibrio Vulnificus* bacteria in raw oysters," as recited in a method step of Claim 6. In fact, the problem of bacterial contamination or solution thereto are not mentioned anywhere in the prosecution history of JP 4356156A.

As submitted above, in *In re Zurko*, 111 F.3d 887, 42 USPQ2d 1476 (Fed. Cir. 1997), the Federal Circuit stressed that "the missing claim elements must necessarily be present in the prior art." Here, an important claim element, elimination of pathogenic *Vibrio Vulnificus* bacteria in oysters, is absent from the cited prior art. It is only through hindsight reconstruction, a practice expressly prohibited by the U.S. patent law, that a parallel may be established between instant Claims 6, 7, and the teachings of the cited reference.

The applicant brings Examiner's attention to the history of the instant application. As Examiner may recall, this application was filed with claims 1-26. In the Office Action of July 21, 1999, Examiner issued a restriction requirement, having identified four distinct Groups of inventions: Group I (claims 1-4, 6, 7) reciting a method of elimination of bacteria; Group II (claims 8-13) reciting a method of shucking of bivalve mollusks;

Group III (claims 14-26) reciting an apparatus for processing raw shellfish; and Group IV (claim 5) reciting a product.

In Examiner's opinion, the inventions of Groups I and II were unrelated (see Office Action of July 21, 1999). Examiner further stated that the inventions were unrelated if it could be shown that they were not disclosed as capable of use together and they had different modes of operation, different functions, or different effects (MPEP 806.04, 808.01).

Based on the conclusion that the inventions are unrelated, have different effects, etc., the Examiner required restriction of the application under 35 USC 121. Following submission of the IDS by the applicant, in a stunning reversal of opinion, Examiner now contends that a method of opening shellfish (similar to Group II) is inherently capable of eliminating pathogenic organisms, i.e. somehow the two methods now have similar modes of operation, similar functions and similar effects. Such inconsistency casts doubt on the propriety of conclusion reached by the Examiner regarding relevancy of JP 4356156A.

The explicit claim limitations for elimination of bacteria must be considered in determination of anticipation. They cannot be ignored. As stated above, the cited reference fails to teach, suggest or show this critical feature of the instant invention, as recited in Claims 6 and 7. The prima facie case of anticipation has not been established, and the submitted evidence, particularly evaluation of the instant invention by persons of ordinary skill in the art, negates Examiner's rejection under 35 USC 102. Consequently, since JP 4356156A does not disclose a method of eliminating bacteria in raw shellfish, it does not anticipate Claims 6 and 7 of the present invention.

Claims 3 and 4 were rejected under 35 USC 103(a) as being unpatentable over JP 4356156A. The Examiner acknowledges that the cited reference does not recite a method of eliminating bacteria and any effect upon pathogenic *Vibriones* bacteria. However, the Examiner concludes that the method steps utilized in the reference are the same as those claimed in Claims 3 and 4, and thus one of ordinary skill in the art would have expected the same results. Examiner further states that the claimed characteristic of eliminating pathogenic *Vibriones* bacteria is considered an inherent property and result of the referenced method, and not unique to the instant invention, absent any clear and convincing evidence or arguments to the contrary.

The applicant respectfully traverses this rejection and submits that obviousness is a legal question based on underlying factual determinations. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1566, 1 USPQ2d 1593, 1596 (Fed. Cir. 1987). Obviousness may not be established using hindsight or in view of the teachings or suggestions of the inventor. *W. L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1551, 1553, 220 USPQ 303, 311, 312-13 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). This is an illogical and inappropriate process. *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 38 USPQ2d 1551 (Fed. Cir. 1996). The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

In addition, such secondary consideration of nonobviousness as commercial success, long felt but unsolved needs, failures of others and copying are considered in determining obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

Obviousness must be established by clear and convincing evidence. *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 45 F.3d 1550, 1555, 33 USPQ2d 1496, 1499 (Fed. Cir. 1995).

As admitted by the Examiner, a method of eliminating pathogenic bacteria is not described in the prior art. Features of Claims 3 and 4 that define and limit the method of eliminating naturally occurring marine bacteria are material features for purposes of distinguishing from the prior art. See, e.g., *Rowe v. Dror*, 112 F.3d 473, 478-79, 42 USPQ2d 1550, 1553-54 (Fed. Cir. 1997); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677-78, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988) (Limitations stated in the preamble limit the claimed invention); *In re Stencel*, 828 F.2d 751, 754-55, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987) (function stated in claim distinguishes from prior art).

As stated above, the cited reference relates to a method of opening shells of raw molluscan shellfish, while Claims 3 and 4 recite a method of eliminating pathogenic organisms. Claim 3 recites, in preamble, " a process of destroying bacteria in raw molluscan shellfish." A method step of Claim 3 recites that the pressure vessel is pressurized "thereby causing elimination of naturally-occurring marine bacteria, while retaining sensory characteristics of " raw shellfish. Claim 4 has a step of exposing raw shellfish "to isostatic pressure for a time period sufficient to eliminate *Vibrio Vulnificus* bacteria."

These claim limitations cannot be ignored. See *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532, 3 USPQ2d 1321, 1324 (Fed. Cir. 1987) (the court cannot ignore a plethora of meaningful limitations). Patentability is

determined for the invention as claimed, with all its limitations. It is improper to delete explicit limitations from the claim in order to find the residue in the prior art.

In equating the function of the method of bacteria elimination with the method of opening shellfish, the Examiner erred and impermissibly used hindsight to arrive at the claimed invention. See *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.").

While in retrospect, looking at applicants' invention, it might seem logical to use high-pressure processing to eliminate pathogenic organisms, the cited reference does not teach this step. Moreover, the enclosed statements from respected scientists attest to the fact that neither of them associated high pressure processing of shellfish with a solution to the problem of eliminating *Vibrio Vulnificus.* These statements discuss the long-felt but unsolved needs of the seafood processing industry, the need that was successfully met by the instant invention.

The applicant further brings attention of the Examiner to the highly detailed statement of Dr. Kilgen that was submitted as part of the Response to the Office Action of July 21, 1999. There, Dr. Kilgen explained the problem of seafood contamination and the uniqueness of the solution offered by the applicant of the present invention.

Consequently, Examiner's opinion that the claimed characteristic of eliminating pathogenic *Vibriones* bacteria is "considered . . . not unique to the instant invention" is not shared by persons having more than ordinary skill in the art.

One having knowledge of JP 4356156A would hardly find it obvious to use the steps of that reference to eliminate bacteria in raw molluscan shellfish while retaining sensory characteristics of raw shellfish. It would not have been obvious to those of ordinary skill in the art to choose the Japanese reference as a solution to the long-existing problem of bacteria contamination because that reference does nothing to educate persons of ordinary skill in the art that the method of the reference could or should be used for bacteria elimination. This position of the applicant is amply supported by statements of persons having more than average skill in the relevant art of seafood processing.

Thus, one must conclude that, on this record, the obviousness of the claimed invention has not been established.

In view of the evidence and arguments presented above, reconsideration of rejection under 35 USC 102 and 35 USC 103(a) and allowance of Claims 3, 4, 6, and 7 is respectfully requested. Should the Examiner feel that a telephone conference would advance resolution of any issues that might remain in the case, he is urged to call the undersigned at the telephone number listed below.

I hereby certified that this correspondence is being deposited with the United States Postal Service as First Class mail in an envelope addressed to:
Commissioner of Patents and Trademarks
Washington, DC 20231

Pamela Gautreaux 9-18-00
Name Date
Pamela Gautreaux Sept. 18, 2000

Respectfully submitted,

Thomas S. Keaty
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EXHIBIT A

LSU AgCenter
Research & Extension

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Department of Food Science
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Baton Rouge, Louisiana 70803-4200
(225)578-5206
Fax: (225)578-5300
Website: www.lsuagcenter.com

September 1, 2000

To Whom it may concern,

I am an Extension food technologist with the Louisiana State University Agricultural Center in Baton Rouge, LA. I have been with LSU for more than 24 years. My doctorate is from Louisiana State University. During that time, I have worked extensively with seafood processors on issues related to process technology, microbiology, and food safety.

The US shell stock oyster industry has been scrutinized for years by public health agencies and consumer groups. The industry is highly regulated by both federal and state governmental agencies responsible for food inspection and safety. It is assumed that shell stock oysters will be eaten raw by consumers, hence the reason for the intense concern. The procedures for inspection of harvesting waters has worked well for decades to minimize the presence of sewage related human pathogens in shell stock oysters. In the 1980's, the discovery of *Vibrio vulnificus* associated with raw molluscan shellfish raised new and important concerns. This organism was not associated with human sewage but is considered to be part of the natural microflora of marine waters. In addition, only identified at-risk individuals (especially those with liver disease) seem to be susceptible to infection. One major goal of the industry and food safety regulatory agencies has focused on the elimination of this pathogen without compromising the integrity of the oyster.

Prior to Mr. Ernie Voisin contacting me about the possibility of using high pressure treatment for the elimination of *Vibrio vulnificus* in raw molluscan shellfish, I was not aware of the process being used anywhere or by anyone for that purpose. In addition, I was not aware of anyone suggesting that the process be used for that purpose prior to Mr. Voisin contacting me. I was invited by Mr. Voisin to assist Dr. Marilyn Kilgen in some preliminary microbiological testing of the process in March, 1998 in Chicago, IL. According to Dr. Kilgen, the process is highly effective in eliminating *Vibrio vulnificus*.

Please let me know if I may be of any further assistance.

Sincerely,

Michael W. Moody, Ph.D.
Seafood Technologist

EXHIBIT B

NATIONAL FISHERIES INSTITUTE

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Arlington, VA 22209
(703) 524-8880 • Fax: (703) 524-4619
www.nfi.org

September 13, 2000

Mike Voisin
Motivatit Seafoods, Inc.
P.O. Box 3916
Houma, LA 70361-3916

Dear Mike,

It was a pleasure seeing you at the ISSC Meeting in July. It certainly reminded me of the meeting in New Orleans last year and the visit to your plant to observe the High Pressure Processing of Oysters to reduce Vibrio vulnificus bacteria.

This new process is truly impressive when you consider the amount of time and money spent by universities and scientist worldwide to solve this concern.

Your dad, Ernest, is to be complimented for having the original idea to treat oysters this way and pursuing it through many hours of testing and fine tuning.

I'm sure the regulators, such as ISSC and FDA, are aware of the importance of this new process.

The oyster industry has been challenged for many years because of Vibrio vulnificus bacteria. This could be one of the breakthroughs needed to correct the problem.

Mike, keep up the good work. If we can be of help, please let us know.

Sincerely,

Robert L Collette

Robert L. Collette
VP of Science & Technology

EXHIBIT C

Translation of Patent 1991-127839 and Supporting Documents

Letter of Request

We, Sato Ichio, Onodera Tetsuyo, and Noishiki Michio, attorneys for the applicant, request that you take responsibility for the following:

(a) all matters concerning the procedures involved in the patent application.

(b) a judgement as to whether the application is accepted or declined.

(c) matters concerning the selection or termination of alternate attorneys.

Notification (from the Patent Office)

Attorney for the Patent Application: Sato Ichio

1991 Patent # 127839

We hereby notify you that we have received a request to review the patent above on January 12th, 1998.

As for patent requests that were received before June 30th, 1995, at which time the 1994 change in the patent law went into effect, one can add specifications or charts to the request within 3 months of our receiving the request, according to the old patent law 17-2-2.

As for patent requests that were received after July 1, 1995, when the 1994 change in the patent law went into effect, one can add specifications or charts at any time before one receives approval or rejection of the patent application, according to patent law 17-2.

When the number of pages of the request increases, for each page that it increases, one must pay 2700 yen for each page that the application increases.

Notification of Reasons for Rejection

Patent Application Number: 1991 #127839

Date of Letter: April 19, 1999

The application has been denied for the following reason. If you have any opinions regarding this matter, please submit them within 60 days from the date that this notification has been sent.

Reason

The invention which corresponds to the page of the application stated below is an invention which has been published in the publication listed below, that has been distributed in Japan and foreign countries before the application, and according to patent law 29-1-3, the patent cannot be accepted.

Notes

Page of Application 1

Document Cited 1

Comments

In Document 1 (1977 #16957), there is a description of the opening of a living shellfish by passing it through a machine that uses high-pressure steam. Because one can say that this is an application of high-pressure on a raw shellfish, there is no structural difference between the invention of the application and the one that Document 1 describes.

Additions

At this point we have not discovered any reason to deny the patent of any other elements of the invention, aside from the one that we have pointed out in this Notification of Rejection. We will inform you, if we find any new reasons for rejection.

Opinions of the Lawyers Regarding the Rejection

1. The patent examiner determined that the patent could not be accepted, according to patent law 29-1-3, because the invention described on page one of our application was an invention described in Patent 1977 #16957.

We have opinions concerning this determination.

2. In our invention our purpose was to provide a method to produce processed shellfish whose shells could easily be opened by hand, and we achieved that goal by using the method of high pressure. According to our application heading 0006, "high pressure" was "pressure above 1000 units of atmospheric pressure." According to the same section "in practice 1000-4000 units is adequate."

We, the applicants, at this time would like to change our application to state clearly that the purpose of the invention is "a method to produce processed shellfish, whose distinguishing characteristic is the application of 1000-4000 units of pressure to a raw unshucked shellfish."

3. In the document cited by the examiner, it states, as pointed out by the examiner, that "the shell of a living shellfish is opened by passing it through a machine that uses high-pressure steam," and that this could be called "the

application of high pressure to a raw shellfish. However, the shucking method described in the cited document involves the "spraying of high-pressure steam," and the standard force of the pressure used is at most 20-30 kg/cm^2. In the cited document, it does not state explicitly what the standard pressure is, but judging from normal technological assumptions, we can assume that the spraying of high pressure steam has a pressure of "at most 20-30 kg/cm^2."

We base this judgement on the following published documents, which have attached as follows.

(1) 1991 3-47649 (citation 1)

(2) 1992 4-31706 (citation 2)

(3) 1989 63-19149 (citation 3)

(4) page 320 of *The Food Industry Dictionary*

(5) page 142-143 of Vol. 4 of *The Food Industry Mechanic Devices Encyclopedia*

(6) page 1-7 of *The Boiler Technology Instruction Manual*

(a) According to citations 1 and 2, which describe machines or devices which reduce bacteria with high-pressure steam, "high-pressure steam" clearly means "saturated steam with a pressure greater than atmospheric pressure."

(b) Moreover, according to references 3 and 4, steam at a temperature of 120-140 °C, and as is evident from the table on page 6 of citation 6, the steam pressure would be 2-4 kg/cm^2.

(c) Furthermore, according to citation 5, the steam pressure that is used is below 10-16 kg/cm^2. This steam would correspond to steam that is below around 180-200 °C.

Citations 1-6 listed above demonstrate that "high pressure" in the technological fields that concern both the method of reducing bacteria with high-pressure steam and the method of spraying high-pressure steam would normally be steam pressure of 2-4 kg/cm^2 or 10-16 kg/cm^2 and even if steam pressure above that level were used, it would be at most 20-30 kg/cm^2.

Therefore, we would like the examiner to understand that the technological basis of our invention, as we explained in section 2 above, i.e. the method of producing processed shellfish which uses high pressure of 1000-4000 kg/cm^2, is not identical to the invention which describes the shucking a shellfish through the use of high pressure steam at most 20-30 kg/cm^2 that the examiner quoted in his rejection of the application.

Also, in contrast to the method the examiner quoted, which describes shellfish meat that is, in the end of the process, steamed, with our method even if you apply 1000-4000 kg/cm^2 of pressure there is no heat used and the meat that is produced by the method remains "raw. (please see paragraphs 0012 and 0013 of our application.)

It would be impossible for our invention and the invention that the examiner quoted to achieve the same results. In other words, our invention produces a result that one cannot imagine to be produced by the invention that the examiner has quoted.

4. Our opinions are as stated above, and we would like the examiner to reexamine the application, basing his review on the explanation of the applicant listed above within the new terms of the application after this revision. We hope that the examiner decides that this invention is worthy of a patent.